# Outcomes of percutaneous biliary stent placement for malignant hilar biliary obstruction

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## Abstract

*Introduction:* This study aims to evaluate the effectiveness and safety of the percutaneous biliary stent placement for malignant hilar biliary obstruction (MHBO).

*Patients and Method:* Percutaneous biliary stent was placed in 50 patients with MHBO at Viet Duc University Hospital from June 2019 to July 2020. The patients were monitored during their hospitalization, at 1-month and long-term follow-up on clinical symptoms and laboratory results as well as complications. The effect and safety of this technique were evaluated.

*Results:* Successful rate was 98%. The total serum bilirubin decreased from 280.06 ± 164.65 µmol/L before to 165.09±112.90 µmol/L one week later ($p<0.001$). Additionally, the AST and ALT significantly decreased ($p<0.001$). Early complication rate was 22.4%, and late complication rate was 2.0% respectively. The stent occlusion rate was 20.4%. The median survival time was 144.2 days.

*Conclusion:* The percutaneous biliary stent placement is a safe and effective palliative therapy for MHBO, helps to improve liver function and quality of life of patients.

## Introduction

Hilar biliary obstruction is mostly due to malignancy including hilar cholangiocarcinoma (Klatskin tumor), intra-hepatic cholangiocarcinoma or gallbladder cancer, hepatocellular carcinomas invading the hilum or metastatic lymph nodes compressing the hepatic hilum. Those pathologies are often with poor prognosis, and curative treatment is challenging. Only 10 - 20% of patients are still indicated for a curative surgical resection of tumor at the time of diagnosis. [1]. Prognosis is often poor, a 5-year survival rate is about 5% [2].

Percutaneous biliary drainage or stent placement is the mini-invasive intervention that helps to improve the quality of life and survival for patients who have no surgical indication. In 1974, biliary drainage was applied for the first time by Mohnar et al. for a palliative treatment for patients with cholangiocarcinoma. [3]. Since then, percutaneous biliary drainage and stent placement have become the fundamental treatment for malignant biliary obstruction if there were no surgical indications to improve patients' survival and quality of life.

Nowadays, the percutaneous biliary stent placement technique has been widely applied. We conducted this study to report our experience in treating malignant hilar biliary obstruction MHBO by percutaneous biliary stent placement to assess it's effect and safety.

## Patients and methods

**Study Subjects:** 50 Patients from June 2019 to July 2020 with HMBO underwent the percutaneous biliary stent in Viet Duc University Hospital enrolled. The patients were diagnosed MHBO but no longer able to be operated even surgical intervention did not resolve the obstruction. The patients with contra-indications such as coagulation disorders, abundant ascites, intra-hepatic biliary stenosis, severe adjacent portal vein stenosis... were excluded.

**Technique performance:**

Step 1: Ultrasound assessment of biliary dilatation, location of obstructive stenosis, and selection of appropriate access.

Step 2: Skin disinfection to selected area, and covered with sterilized drape from the chest through abdomen until lower extremities of patients leaving a hole for intervention.

Inserting a 16-G needle into the selected biliary duct under ultrasound guidance. Implementing a cholangiography with DSA to identify the stenosis location.

Step 3: Slipping the 0.035" guide wire through stenosis location towards the duodenum, slipping a 5F cobra catheter, removing the guidewire, and implementing another cholangiography to confirm the length of stenosis. Depending on the obstruction location, severity, and length for proper selection of stent.

Step 4: Slipping a tough 0.0035" guide wire (Amplatz) via stenosis towards the duodenum.

Step 5: Placing the stent to ensure that its upper and lower tips are covered at least 1 cm over the stenosis. That's the metal self-expandable therefore no need for a dilatation balloon.

Step 6: Inserting an 8.5F biliary drainage into the biliary duct for cholangiography check. Fix the drain and connect to the external system.

Step 7: Cholangiography for check and removal of drain on the seventh day after the intervention.

**Collecting and analyzing the database:**

The information was collected including the characteristics of study group, blood test results before the intervention, including serum bilirubin, hepatic functional tests, and imaging diagnosis. Monitoring patients during their hospitalization, at 1-month and more-than-3-month check-up to evaluate changes of clinical symptoms, blood tests as well as complications during hospitalization, late complications, improvement the quality of life by using ECOG scale and survival rates

The data was analyzed using SPSS 20.0 software.

## Results

**Characteristics of study subjects**

From June 2019 to July 2020, 50 patients with MHBO who underwent biliary stent percutaneously enrolled. The details were described in Table 1.

Table 1. General characteristics of study subjects

| Age | | 65±13 (31-98 years-old) | |
|---|---|---|---|
| Description | | Number of patients (n) | Rate (%) |
| Gender (Male/female) | | 29/21 | 58/42 |
| Tumor type | Klatskin tumor | 36 | 72 |
| | Intrahepatic cholangiocarcinoma | 5 | 10 |
| | Hepato-cellular carcinomas | 4 | 8 |
| | Invasive gallbladder cancer | 3 | 6 |
| | Hilar metastatic adenopathy | 2 | 4 |
| Bismuth – Corlette Classification | I | 1 | 2.8 |
| | II | 6 | 16.7 |
| | IIIa | 3 | 8.3 |
| | IIIb | 7 | 19.4 |
| | IV | 19 | 52.8 |
| CA 19-9 (U/ml) | | 5613.9 | |

**Outcomes of percutaneous biliary stent placement**

Of a total of 50 patients, 49 patients were stented successfully with the success rate accounted for 98%. Most of cases were inserting the stents from right intrahepatic biliary duct with 39/49 patients, accounting for 79.6%. 1 patient (2.0%) was stenting from both sides. 35 patients were stenting with uncoated stents (71.4%), 10 patients with coated stents (20.4%) and 4 patients stented by both types (8.2%).

Mean level of serum bilirubin and transaminase before, right after and at 1 week after intervention were described in Table 2.

Table 2. Concentration of serum bilirubin and liver function tests before and after the intervention

| Descriptions | Before (n=50) | After 1 day (n=49) | After 1 week (n=49) |
|---|---|---|---|
| Total Bilirubin (µmol/l) | 280.06±164.65 | 235.02±129.79 (p=0.003) | 165.09±112.90 (p<0.001) |
| AST (U/L) | 133.41±90.56 | 81.44±51.06 (p<0.001) | 61.73±43.23 (p<0.001) |
| ALT (U/L) | 126.58±107.28 | 78.54±62.22 (p<0.001) | 55.46±49.23 (p<0.001) |

The mean total bilirubin level after one day and one week of intervention was decreased significantly compared to before the intervention with a p-value of 0.003 and <0.001, respectively. At one month after intervention, the mean concentration of bilirubin was 51.36 µmol/l, with a reduction of 81.7% compared to the initial values. Liver function was improved remarkably with the reduction of AST and ALT concentration after the intervention. Clinically, after one week, jaundice was reduced obviously in most cases (91.8%), except 4 cases with no obvious improvement. However, after one month,100% of patients no longer jaundice sign or remarkably decreased.

The mean of hospital stay was 13 days, the shortest being seven days, and the longest being 40 days.

Table 3. Complications after percutaneous biliary stent placement

| Description | | Number (n) | Rate (%) |
|---|---|---|---|
| Early complication | Fever | 3 | 6.1 |
| | Biliary hemorrhage | 4 | 8.2 |
| | Pleural effusion | 2 | 4.1 |
| | Acute pancreatitis | 1 | 2.0 |
| | Intra-abdominal hemorrhage | 1 | 2.0 |
| Late complication | Hepatic abscess | 1 | 2.0 |
| Obstruction of stent | | 10 | 20.4 |

The early complication rate was 22.4%, including: fever (n=3), biliary hemorrhage (n=4), pleural effusion (n=2), acute pancreatitis (n=1), intra-abdominal hemorrhage (n=1). The late complication rate was 2.0%, including hepatic abscess (n=1). The rate of stent obstruction accounted for 20.4% (n=10) with a mean time of 6.45 months; the shortest being two months, and the longest being 10.5 months and they were all re-stented for second time.

Table 4. Changes of quality of life

| Description | Before | After 1 month | P value |
|---|---|---|---|
| ECOG | 3.00 | 1.41 | < 0.001 |

The mean survival time was 144.2 days, the shortest being seven days, and the longest being 378 days.

## Discussion

*Percutaneous biliary stent placement* is an effective palliative treatment for MHBO. The success rate in our study was 98%, similar to other authors such as Li M. (100%), Perdue D.G. (97%) [4],[5]. Among 50 patients, there was 1 case failed because of a severe dilatation of the intrahepatic biliary duct due to longtime biliary obstruction, which created an obtuse angle at the transition point leading to difficulties in slipping

the guidewire through the stenosis. For those cases, biliary drainage several days before stent placement recommended which might reduce the pressure of biliary tract and the severity of biliary dilatation.

Biliary drainage from one part of the liver could give the same results of the whole liver drainage. The guidance of the Asia-Pacific Association for the study of the liver (APASL) commended to drain at least 50% of liver volume [6]. In most cases, the stent was placed from the right side (79.6%) because the volume of the right liver was large, so the biliary drainage should be more effective than from the left side. The stent was placed from the left side in some cases when the tumor already invaded deeply into the right liver's biliary branches or with a hypertrophy left liver. All those cases were with good results even though the right liver was not drained. In some cases, two stents were inserted from the anterior and posterior branches or both sides of the intrahepatic biliary duct towards the common bile duct. If the tumors has invaded into the intrahepatic biliary duct, there was no bile flow between biliary branches anymore, and one stent placement would not completely resolve the problems.

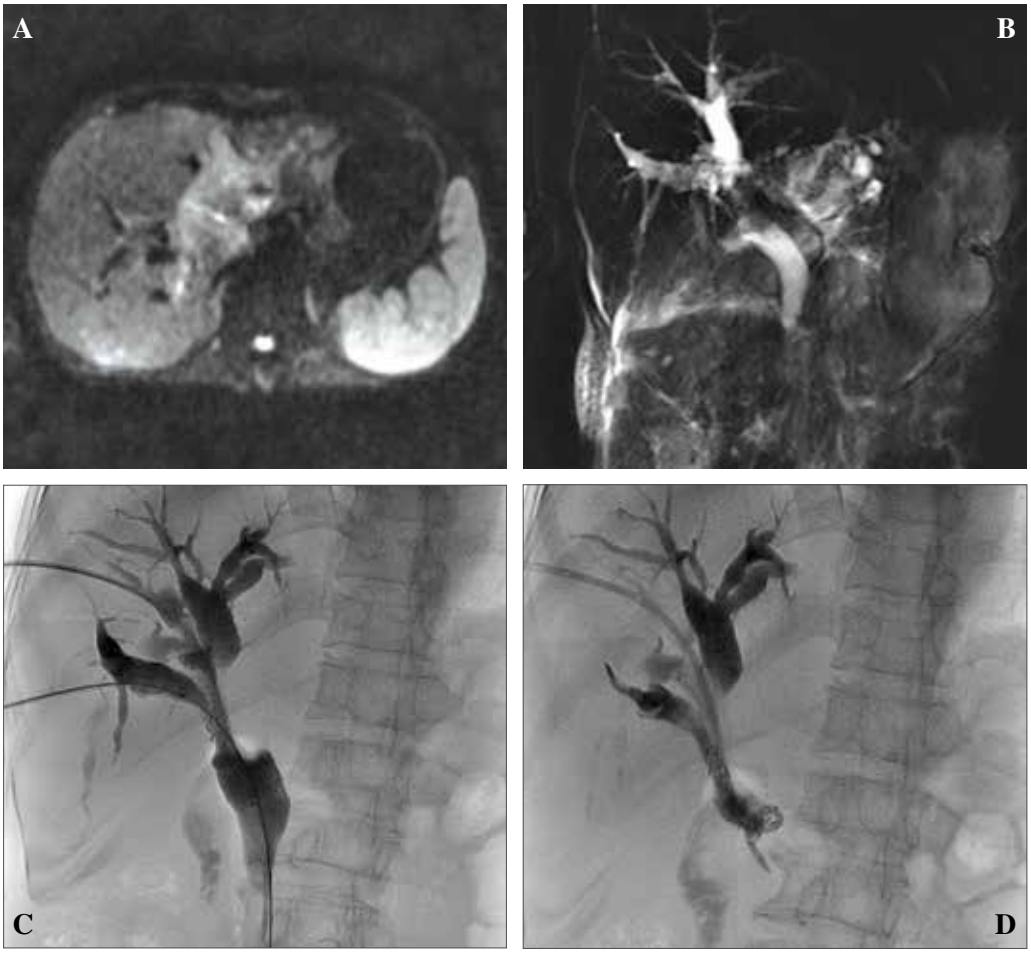



Figure 1. 61-year-old female patient, medical record code: 6348

Intrahepatic cholangiocarcinoma that invaded the liver hilum: the tumor was with limited diffusion in DWI (A), invaded and constricted the biliary confluence (B) 2 uncoated stents of 10x60mm in size were inserted from the anterior and posterior biliary duct downwards (C), exteriorizing 8.5F drain placement (D).

Two techniques developed for the percutaneous bilateral biliary stents were stent-in-stent (SIS) and stent-by-stent (SBS). In the SBS technique, two metal stents were inserted parallel to drain the biliary duct of both hepatic lobes. However, this parallel placement might impact to the complete expansion of metal stents at and below the biliary hilar sites. In the SIS technique, the second stent was placed through the mesh of the 1st stent to go into the common bile duct to assure a complete expansion of both stents inserted. With this technique, two stents might be placed in a Y- or T-shape => hình như sai tiếng Việt ?? with no significant difference in technical success and complication rate. The deployment of the T-shaped SIS technique for bilateral biliary drainage was more appropriate for patients with MHBO but more challenging techniques than Y-shaped double stent placement [7].

In our series, self-expandable metal stents (SEMS) were used because they had a bigger diameter and high ability to re-circulate the bile in comparison with plastic stents. There were ten patients inserted with stents coated by PTFE, 35 patients with uncoated stents, and remaining 4 patients inserted by both coated and uncoated stents. According to Shiro [7], the expandable level of SEMS was outstanding and independent with PTFE coating or not. In all cases of our study, stents were well expandable. PTFE-coated stents were used to prevent the tumor invading into the stents' lumen so that it might improve the duration of the stent's functional operation. Stent selection is depending on the location of the tumor that caused the biliary obstruction. Coated stents are used to Klatskin tumors of type I, II according to Bismuth. Vice versa, when the tumor invaded upwards, the usage of the coated stent might lead to a risk of minor drainage causing cholangitis is not drained biliary branches.

The mean level of serum total bilirubin before intervention in the study was 280.06 ± 164.65 µmol/l, 14 times higher than the normal range. The rate of mostly or entirely regression of jaundice (91.8%) as well as of the reduction of serum bilirubin level after the intervention was relatively high, with the mean reduction of more than 75% after one month showing good effectiveness of the percutaneous biliary stent placement and good drainage of the biliary juice.

Early complications after stent placement were recorded in 20.4% , including fever, biliary hemorrhage, intra-abdominal hemorrhage, pleural effusion, acute pancreatitis; among them, there were mostly mild complications. Two cases with severe complications were recorded, including one case with high fever due to cholangitis with pustular bile discharge and 1 case of intra-abdominal hemorrhage due to a vascular injury when injecting, well controlled by embolization under DSA. Our results were similar to those of author Li M. (early complication rate of 26.4%) [4]. However, no mortality related to the intervention was recorded. The late complication in our series was one case developed hepatic abscess three months later causing by S. aureus, requiring drainage with good outcome.



Figure 2. 62-year-old female patient, medical record code: 38636
A complication of a hepatic abscess at three months after biliary stent placement via the right hepatic duct: a hypodensity fluid collection.

During long-term follow-up, we recognized that patients' quality of life was considerably improved (the mean ECOG score decreased from 3.0 to 1.4), among them, almost of cases were able to come

back to their daily life activities (ECOG score of 1-2 points) without support from relatives. Those results were similar to those of Li M., with the mean ECOG score reduction from 3.17 to 1.41 [4].

The stents might be obstructed with a rate from 19 % to 40%, depending on the survival time of patients and study duration [8]. Stent obstruction was due to biliary sludge deposition or malignant progression into stents' lumen and led to recurrent biliary obstruction. Clinical manifestations of stent obstruction was recurrent jaundice with images of an intrahepatic biliary dilatation and maybe images of a biliary sludge deposition or an intra-luminal solid tissue. There were 10 cases of metal stent obstruction at an average of 6.45 months (20.4%) after the intervention, similar to the results of Nguyen Quoc Dung (the rate of stent obstruction of 21%) [10].

There are some limitations of study. The first one is a small sample size with a not long enough follow-up. The second is the loss of contact with some patients during follow-up, so the survival rate after the intervention was not fully assessed, and effectiveness comparison was not made between coated and uncoated stent groups.

## Conclusion

The study showed that the percutaneous biliary stent placement was a mini-invasive intervention with safety and effectiveness in the treatment of MHBO, could improve patients' clinical symptoms as well as quality of life.

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